

nervous system on cardiovascular activities, including vagal and sympathetic components.

The aim of this study was to evaluate changes in HRV induced by BoNT-A (NT-201) injection in spastic stroke patients.

Methods.— Eleven stroke survivors with spastic hemiplegia were injected with IncobotulinumtoxinA (100 units:2 mL of 0.9% NaCl), with doses \geq 600 UI (maximal dose < 12 UI/Kg). They received two ECG registrations of 30 min each, the first 24 h before injection and the second 10 days after. Linear and non-linear HRV variables were obtained with HRV analysis software.

Results.— None of the variable considered for time, frequency domain and non-linear domain suffer significant changes after BoNT-A injection.

Conclusions.— High doses of BoNT-A do not influence cardiac autonomic drive. Moreover, no clinical adverse events of any kind occurred in anyone of our patients after NT-201 injection.

<http://dx.doi.org/10.1016/j.rehab.2014.03.170>

P211-e

Incobotulinum booster injections in patients with spasticity and dystonia after stroke

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Keywords: Spasticity; Stroke; Dystonia; Incobotulinum toxin A; Booster injection

Background.— Previous results in patients injected with abobotulinum toxin A and onabotulinum toxin A have shown that injection intervals shorter than 2 months may increase the risk for neutralising antibody formation and treatment non-response. As a result, for the last 10 years, we have adopted longer intervals to treat patients with spasticity and/or dystonia secondary to stroke. It has been showed that incobotulinum toxin A does not induce neutralising antibodies.

Observations.—

Methods.— Ten patients with spasticity and/or dystonia due to stroke underwent a booster injection one month after the first injection. The clinical results were compared to those previously obtained in the same 10 patients using a single injection. Secondary dystonia was evaluated using the Unified Dystonia Rating Scale (UDRS), while spasticity was evaluated according to the Modified Ashworth Scale (MAS).

Results.— They showed that the booster injection protocol induced an improvement in 8 subjects. In the remaining 2 subjects, we did not find any difference between the results obtained using the single and the booster injection protocols.

Conclusions.— The use of a booster injection improve the clinical outcome in patients with spasticity and/or dystonia after stroke, allowing an optimal treatment of those muscles that poorly responded to the first injection.

<http://dx.doi.org/10.1016/j.rehab.2014.03.171>

P212-e

SPACE, interim analyses of an international, non-interventional study of botulinum toxin treatment for spasticity

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OnabotulinumtoxinA; AbobotulinumtoxinA

Background.— SPACE, an international, non-interventional study, is collecting effectiveness, safety and quality of life (QoL) data on botulinum toxin type A (BoNT-A) treatment for spasticity in a routine practice setting. Here, we present interim analyses of the first treatment cycle.

Methods.— BoNT treatment-naïve adults with spasticity of any aetiology were followed for up to 2 years. Data collected include global assessments of efficacy (patient-rated [PGAE] and investigator-rated [IGAE]) and investigator global assessment of tolerability (IGAT). Global assessments were made at the end of the first treatment cycle and scored from 1 = very good to 4 = poor. PGAE/IGAE responders were defined as patients with scores \leq 3 = moderate.

Results.— The interim analyses include 648 patients^{*} (61.9% male, mean [standard deviation] age 54.8 [15.6] years) who received 1 treatment cycle with incobotulinumtoxinA (n = 435), onabotulinumtoxinA (n = 138) or abobotulinumtoxinA (n = 75). Overall, 468/510 (91.8%) patients were PGAE responders and 476/500 (95.2%) patients were IGAE responders. IGAT was very good or good for 467/500 (93.4%) patients.

^{*}Interim analyses – data were not yet available for all patients

Conclusions.— For patients with focal spasticity, their first-ever BoNT-A treatment cycle was efficacious and well tolerated. Longer-term data will assess the benefits of BoNT-A injections over multiple treatment cycles.

<http://dx.doi.org/10.1016/j.rehab.2014.03.172>

P213-e

Efficacy of incobotulinum toxin A (Xeomin®) in the treatment of dynamic equinus foot in children with hemiplegic cerebral palsy

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Keywords: Cerebral palsy; Spasticity; Incobotulinum toxin A

Background.— Previous studies have shown the efficacy of botulinum toxin type A (BoNT-A) in the management of ambulant individuals with cerebral palsy (CP). We evaluated the efficacy of incobotulinum toxin A (Xeomin®) injections in children with dynamic equinus affected by hemiplegic CP in polycentric study.

Methods.— The efficacy of treatment was tested in 30 children aged from 2 to 18 years with spasticity more than 2 at Modified Ashworth Scale, injections were performed in calf muscles up to 200 U, with electromyographic guidance. The treatment efficacy was evaluated with the Modified Ashworth Scale, Tardieu Scale, Active and Passive Range of motion and Walking test on 10 m. Clinical data were collected at time 0 and at 1, 3 and 6 months after the injections.

Results.— Preliminary data showed good efficacy and tolerability of treatment spasticity with botulinum toxin A in children.

Conclusions.— Incobotulinum toxin A seems to be as effective as other type A botulinum toxins. The absence of proteins could be an advantage in the paediatric population requiring repeated treatments over time.

<http://dx.doi.org/10.1016/j.rehab.2014.03.173>

P214-e

TOWER: Design of an open-label incobotulinumtoxinA dose-titration study (up to 800 U) in lower and upper limb spasticity

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